SAFETY DATA SHEET

1. Identification

Product identifier: Cosyntropin Acetate

Other means of identification:
- Catalog number: 1150115
- CAS number: 16960-16-0
- Synonyms: Tetracosactrin * Tetracosactide
- Chemical name: alpha^1-24-Corticotropin

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790

RS Technical Services: 301-816-8129

Emergency phone number
- CHEMTREC within US & Canada: 1-800-424-9300
- CHEMTREC outside US & Canada: +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Sensitization, respiratory: Category 1
- Sensitization, skin: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Signal word: Danger

Hazard statement: May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement


Response: If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.

Storage: Not available.

Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): None known.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosyntropin Acetate</td>
<td>Tetracosactrin</td>
<td>16960-16-0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tetracosactide</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. If experiencing respiratory symptoms: Call a poison center or doctor/physician.

Skin contact
Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Most important symptoms/effects, acute and delayed
Provide general supportive measures and treat symptomatically. Keep victim under observation.

Indication of immediate medical attention and special treatment needed
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

**Occupational exposure limits**  
No exposure limits noted for ingredient(s).

**Biological limit values**  
No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**  
No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**  
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection**

**Hand protection**  
Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Other**

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**  
Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

**Appearance**  
Appearance descriptions are general information and not specific to any USP lot.

**Physical state**  
Solid.

**Form**  
Powder.

**Color**  
White. Off-white.

**Odor**  
Not available.

**Odor threshold**  
Not available.

**pH**  
Not available.

**Melting point/freezing point**  
Not available.

**Initial boiling point and boiling range**  
Not available.

**Flash point**  
Not available.

**Evaporation rate**  
Not available.

**Flammability (solid, gas)**  
Not available.

**Upper/lower flammability or explosive limits**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Vapor pressure**  
Not available.

**Vapor density**  
Not available.

**Relative density**  
Not available.

**Solubility(ies)**

| Solubility (water) | Sparingly soluble |

**Auto-ignition temperature**  
Not available.
Decomposition temperature  
Not available.

Viscosity  
Not available.

Other information  
Molecular formula  
C136H210N40O31S  
Molecular weight  
2933.57

10. Stability and reactivity  
Reactivity  
The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability  
Material is stable under normal conditions.
Possibility of hazardous reactions  
No dangerous reaction known under conditions of normal use.
Conditions to avoid  
Contact with incompatible materials.
Incompatible materials  
Strong oxidizing agents.
Hazardous decomposition products  
NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information  
Information on likely routes of exposure  
Inhalation  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact  
May cause an allergic skin reaction.
Eye contact  
Knowledge about health hazard is incomplete.
Ingestion  
Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics  

Information on toxicological effects  
Acute toxicity  
Not known.
Skin corrosion/irritation  
Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation  
Knowledge about health hazard is incomplete.
Respiratory or skin sensitization  
Respiratory sensitization  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization  
May cause an allergic skin reaction.
Germ cell mutagenicity  
Knowledge about mutagenicity is incomplete.
Carcinogenicity  
Knowledge about carcinogenicity is incomplete.
IARC Monographs. Overall Evaluation of Carcinogenicity  
Not listed.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)  
Not regulated.
US. National Toxicology Program (NTP) Report on Carcinogens  
Not listed.
Reproductive toxicity  
Knowledge about health hazard is incomplete.
Specific target organ toxicity - single exposure  
Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure  
Knowledge about health hazard is incomplete.
Aspiration hazard  
Based on available data, the classification criteria are not met.
Further information  
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information  
Ecotoxicity  
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability  
No data is available on the degradability of this substance.
Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

General information
It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Yes

Classified hazard categories
Respiratory or skin sensitization

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
US state regulations

California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s). A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date: 12-21-2012
Revision date: 06-11-2019
Version #: 04

Disclaimer

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